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December 20, 2005

Division of Dockets Management (HFA-305) Food and Drug Administration 5630 Fishers Lane Room 1061 Rockville, MD 20852

Re: Docket No: 2002N-0273 (formerly Docket No. 02N-0273)

Substances Prohibited From Use in Animal Food and Feed

Dear Sir or Madam:

The American Farm Bureau Federation (AFBF) appreciates the opportunity to submit comments on this important proposed rule. After the identification of bovine spongiform encephalopathy (BSE) in indigenous North American cattle, the U.S. Department of Agriculture (USDA) responded rapidly to implement measures to protect animal and public health. Our members recognize the importance of and strongly support the ruminant-to-ruminant feed ban that went into effect in August 1997. Given what is currently known about the epidemiology and characteristically long incubation period of BSE, we agree that it is appropriate for the Food and Drug Administration (FDA) to implement additional measures which will minimize the risk of BSE recycling in the U.S. cattle herd.

AFBF fully supports the intent of the proposed rule. We agree that by removing the bovine tissues most likely to contain high levels of infectivity from all animal feed, the level of safety in the remaining feed components is increased. Specifically, we support extending to all livestock, poultry and pet feed the current ruminant ban on brain and spinal cord material from bovines 30 months of age and older.

FDA has also proposed prohibiting the entire carcass of cattle not inspected and passed for human consumption if the brains and spinal cords cannot be removed. It will allow these carcasses into the feed chain if brain and spinal cord can be removed. It is with this provision that we urge caution.

Clearly, it will be difficult to remove brain and spinal cord from dead stock, especially in warm and hot weather. Yet, removal of the brain and spinal cord from these animals is essential. Leaving the highest risk tissues from these cattle in the animal feed chain would effectively nullify the intent of this regulation. This point is illustrated by the 2001 Harvard risk assessment model which demonstrated that eliminating dead and downer (4D) cattle from the feed stream was a disproportionately effective means of reducing the risk of re-infection.

"The disposition of cattle that die on the farm would also have a substantial influence on the spread of BSE if the disease were introduced." The base case scenario showed that the mean total number of ID50s (i.e., dosage sufficient to infect 50 percent of exposed cattle) from healthy animals at slaughter presented to the food/feed system was 1500. The mean total number of ID50s from adult cattle deadstock presented to the feed system was 37,000. This illustrates the risk of "4D cattle" (i.e., deadstock).

From the Harvard Risk Assessment, 2001, Appendix 3A Base Case and Harvard Risk Assessment, 2001 Executive Summary

We also question the ability of the government to enforce this regulation. Unlike slaughter facilities where government inspectors are present on a continual basis, there is no continual inspection at rendering or dead stock collection facilities. FDA should further explain how they intend to enforce this exemption in the event it is included in the final rule.

Production agriculture understands that compliance with the current feed ban is imperative. As we previously noted in our comments to the Advanced Notice of Proposed Rulemaking (ANPR), proper labeling information is key to the individual producer's ability to comply with the intent of the feed ban. Although the proposed rule does not address any labeling issues, we feel that some changes to the labels required on animal feed may assist with on-farm compliance. We encourage FDA to consider the following labeling issues in any future action regarding the ruminant feed ban.

Livestock feed labels should provide clear, concise and accurate information regarding ingredients and nutritional information. We believe FDA and state feed control officials should consider making modifications in labeling requirements by developing more specific classifications of animal protein sources such as "non-ruminant derived animal proteins," "ruminant derived animal proteins" and "non-mammalian derived animal proteins" to provide producers with the information they need to make the certifications about feeding practices that the marketplace is demanding. We do not believe that it is necessary to label feed ingredients according to species origin. We support the use of the current warning statement of feed labels that states "Do not feed to cattle or other ruminants" if the feed contains ingredients prohibited to be fed to ruminants by FDA rules.

The American Farm Bureau Federation will continue to work with the FDA and other government agencies to implement a strong BSE risk control program that is based on scientific facts and has a practical application. Thank you for the opportunity to submit these comments to the public record.

Sincerely,

Mark Maslyn
Executive Director

Public Policy